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the presence of ST receptor protein in said test sample above the presence of ST receptor protein in said negative control sample indicates that said individual has metastasized colorectal cancer.

Claim 10 (New). The method of claim 9 wherein

said test assay is an immunoassay to detect ST receptor protein comprising ST receptor protein-specific detectable antibodies that are contacted with said test sample, and

said negative control assay is an immunoassay to detect ST receptor protein comprising ST receptor protein-specific detectable antibodies that are contacted with said negative control sample.

Claim 1 (New).

The method of claim wherein said sample is body fluid.

Claim 12 (New). The method of claim 11 wherein said sample is blood.

The method of claim of further comprising the step of performing a positive control assay on a positive control sample to detect ST receptor protein present in said positive control sample.

An in vitro method of determining whether or not an individual has metastasized colorectal cancer comprising the steps of:

a) performing a test assay on a test sample of extraintestinal tissue and/or body fluids



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from an individual to detect mRNA encoding ST receptor protein present in said test sample;

- b) performing a negative control assay on a negative control sample to detect mRNA encoding ST receptor protein present in said negative control sample;
- c) comparing results of said test assay with results of said negative control assay, wherein the presence of mRNA encoding ST receptor protein in said test sample above the presence of mRNA encoding ST receptor protein in said negative control sample indicates that said individual has metastasized colorectal cancer.

Claim 15 (New). The method of claim 14 wherein

said test assay comprises amplification of mRNA by polymerase chain reaction, and said negative control assay comprises amplification of mRNA by polymerase chain reaction.

Claim 16 (New). The method of claim 14 wherein said sample is body fluid.

Claim 17 (New). The method of claim 18 wherein said sample is blood.

Claim 18 (New). The method of claim 14 further comprising the step of performing a positive control assay on a positive control sample to detect mRNA encoding ST receptor protein present in said positive control sample.

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Claim 19 (New). An *in vitro* assay kit for determining whether or not an individual has metastasized colorectal cancer by detecting the presence of ST receptor protein in a sample of extraintestinal tissue and/or body fluids from an individual, said kit comprising:

a container comprising antibodies specific for ST receptor protein; instructions for using said kit, said instructions indicating steps for

performing a method to detect the presence of ST receptor protein in said sample and

analyzing data generated by said method, wherein said instructions indicate that the presence of ST receptor in said sample indicates that the individual has colorectal cancer.

Claim 20 (New). The kit of claim is further comprising a container that comprises a detectable antibody that binds to said antibodies specific for ST receptor protein.

Claim (New). An *in vitro* assay kit for determining whether or not an individual has metastasized colorectal cancer, said kit comprising:

a container comprising antibodies specific for ST receptor protein;

a container comprising a negative control sample;

instructions for using said kit, said instructions indicating steps for

performing a test assay to detect the presence of ST receptor protein in a test sample of extraintestinal tissue and/or bodily fluid from said individual,

performing a negative control assay to detect the presence of ST receptor protein



in said negative control sample and

comparing data generated by said test assay and negative control assay, wherein said instructions indicate that the presence of ST receptor in said test sample above the presence of ST receptor in said negative control sample indicates that the individual has colorectal cancer.

Claim 22 (New). The kit of claim 21 further comprising a container that comprises a detectable antibody that binds to said antibodies specific for ST receptor protein.

Claim 23 (New). An *in vitro* PCR assay kit for determining whether or not an individual has colorectal cancer by detecting the presence of mRNA that encodes ST receptor protein in a sample of extraintestinal tissue and/or body fluids from an individual, said kit comprising:

a first container comprising PCR primers that specifically amplify mRNA that encodes ST receptor protein;

a second container comprising a size marker, said size marker being the expected size of amplified DNA if said mRNA that encodes ST receptor protein is present in said sample; and

performing a method to detect the presence of mRNA that encodes ST receptor protein in said sample and

instructions for using said kit, wherein said instructions indicate steps for

analyzing data generated by said method, wherein said instructions indicate that the presence of mRNA that encodes ST receptor protein in said sample indicates that the individual has colorectal cancer.

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Claim 24 (New). An *in vitro* assay kit for determining whether or not an individual has metastasized colorectal cancer, said kit comprising:

a first container comprising PCR primers that specifically amplify mRNA that encodes ST receptor protein;

a second container comprising a size marker, said size marker being the expected size of amplified DNA of mRNA that encodes ST receptor protein;

a third container comprising a negative control sample;

and

instructions for using said kit, wherein said instructions indicate steps for

performing a test assay to detect the presence of mRNA that encodes ST receptor protein in a test sample of extraintestinal tissue and/or bodily fluid from said individual,

performing a negative control assay to detect the presence of mRNA that encodes ST receptor protein in said negative control sample and

comparing data generated by said test assay and negative control assay, wherein said instructions indicate that the presence of mRNA that encodes ST receptor in said test sample above the presence of mRNA that encodes ST receptor in said negative control sample indicates that the individual has colorectal cancer.

## **REMARKS**

This application is a continuation application filed herewith pursuant to 37 C.F.R. 1.53(b). The parent application, Serial Number 08/789,270 filed January 28, 1997, has been